SEP 27 2002 K022901

Summary Information

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: _____.

1. **Submitter name, address, contact**

Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Drive
Rochester, New York 14626-5101
(585) 453-4041

Contact Person: Marlene A. Hanna

2. **Preparation date**

Date Special 510(k) prepared: 30 August 2002

3. **Device name**

Trade or Proprietary Name:
VITROS Immunodiagnostic Products Progesterone Reagent Pack
VITROS Immunodiagnostic Products Progesterone Calibrators

Common Name : Progesterone assay
Classification Name: Progesterone test system (21 CFR 862.1620).

4. **Predicate device**

The VITROS Immunodiagnostic Products Progesterone Reagent Pack (new formulation) and VITROS Immunodiagnostic Products Progesterone Calibrators (new formulation) are substantially equivalent to the VITROS Immunodiagnostic Products Progesterone Reagent Pack (original formulation) and VITROS Immunodiagnostic Products Progesterone Calibrators (original formulation).

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5. Device description

The VITROS Immunodiagnostic System uses luminescence as the signal in the quantitative and semi-quantitative determination of selected analytes in human body fluids, commonly serum and plasma. Coated microwells are used as the solid phase separation system.

The system is comprised of three main elements:

1. The VITROS Immunodiagnostic Products range of immunoassay products (in this case VITROS Immunodiagnostic Products Progesterone Reagent Pack, VITROS Immunodiagnostic Products Progesterone Calibrators, which are combined by the VITROS Immunodiagnostic System to perform the VITROS Progesterone assay.

2. The VITROS Immunodiagnostic System – instrumentation, which provides automated use of the immunoassay kits. The VITROS Immunodiagnostic System was cleared for market by a separate 510(k) pre-market notification (K962919).

1. Common reagents used by the VITROS System in each assay. The VITROS Immunodiagnostic Products Signal Reagent and VITROS Immunodiagnostic Products Universal Wash Reagent were cleared as part of the VITROS Immunodiagnostic Products Total T3 Reagent Pack and VITROS Immunodiagnostic Products Total T3 Calibrators 510(k) premarket notification (K964310).

The VITROS System and common reagents are dedicated specifically for use only with the VITROS Immunodiagnostic Products range of immunoassay products.

6. Device intended use

VITROS Progesterone Reagent Pack
For in vitro diagnostic use only.
The VITROS Progesterone Reagent Pack quantitatively measures Progesterone concentration in human serum and plasma.

VITROS Progesterone Calibrators - For *in vitro* use in the calibration of the VITROS Immunodiagnostic System for the quantitative measurement of Progesterone in human serum and plasma (EDTA or heparin).

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7. Comparison to predicate device

The VITROS Immunodiagnostic Products Progesterone Reagent Pack (modified) and VITROS Immunodiagnostic Products Progesterone Calibrators (modified) are substantially equivalent to VITROS Immunodiagnostic Products Progesterone Reagent Pack and Calibrators cleared by the FDA (K972133) for in vitro diagnostic use.

Table 1 lists the assay characteristics performed using the modified VITROS Progesterone assay and the current VITROS Progesterone assay.

Table 1: List of Assay Characteristics: Comparison to Predicate Device

Device Characteristic	Predicate Device VITROS Progesterone assay (Current)	New Device VITROS Progesterone assay (Modified)
Number of Calibrators	2	3
Nominal Calibrator values	3.40 and 137 nmol/L	0.0, 4.25, 120 nmol/L
Calibration range	0 to178 nmol/L	0 to178 nmol/L
Sample type	Serum and plasma (EDTA or heparin).	Serum and plasma (EDTA or heparin).
Antibody	Rabbit polyclonal anti-progesterone antibody in biotinylated antibody reagent	Rabbit polyclonal anti-progesterone antibody in biotinylated antibody reagent
Basic principle	Solid phase immunoassay	Solid phase immunoassay
Tracer	Enzyme labeled	Enzyme labeled
Instrumentation	VITROS Immunodiagnostic System	VITROS Immunodiagnostic System
Sample volume	25µL	25µL
Incubation time and temperature	16 minutes at 37°C with shaking	16 minutes at 37°C with shaking

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8. Conclusions

The information presented in the pre-market notification demonstrates that the performance of the VITROS Progesterone assay (modified) for use with human serum and plasma is substantially equivalent to the cleared predicate device.

Equivalence was demonstrated using manufactured reagents along with patient samples with measured Progesterone values spanning the assay range.

The information presented in the premarket notification provides a reasonable assurance that the VITROS Progesterone assay (modified) for use with human serum and plasma is safe and effective for the stated intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 27 2002

Ms. Marlene A. Hanna
Regulatory Affairs Associate
Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Drive
Rochester, NY 14626-5101

Re: k022901
Trade/Device Name: VITROS Immunodiagnostic Products Progesterone Reagent Pack
VITROS Immunodiagnostic Products Progesterone Calibrators
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Code: JIS
Dated: August 30, 2002
Received: September 3, 2002

Dear Ms. Hanna:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Intended Use

510(k) Number (if known): K022901

Device Name:

VITROS Immunodiagnostic Products Progesterone Reagent Pack
VITROS Immunodiagnostic Products Progesterone Calibrators

Indications for Use:

VITROS Progesterone Reagent Pack
For in vitro diagnostic use only.
The *Vitros* Progesterone Reagent Pack quantitatively measures progesterone concentration in human serum and plasma.

VITROS Progesterone Calibrators - For *in vitro* use in the calibration of the VITROS Immunodiagnostic System for the quantitative measurement of Progesterone in human serum and plasma (EDTA or heparin).

(Division)
Division ... ratory Devices
510(k) Number K022901

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)